

MedSun: Newsletter #40, September 2009

Articles

Philips Avalon Fetal Monitors

[Print Item](#)
[E-mail Item](#)

FDA MedWatch Safety Alert

FDA issued a Dear Healthcare Provider Letter to notify healthcare professionals and facilities of a number of complaints of inaccurate readings when using the Philips Avalon Fetal Monitors, Models FM20, FM30, FM40, and FM50 with the ultrasound transducer. On September 4, 2009, Philips issued an Important Device Safety Alert. Inaccurate output readings, if not properly addressed, may lead to unnecessary interventions, failure to identify the need for interventions, and failure to identify fetal distress.

Additional Information:

FDA MedWatch Safety Alert. Philips Avalon Fetal Monitors. September 4, 2009.
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181505.htm>⁷

FDA Dear Healthcare Provider Letter. Philips Avalon Fetal Monitors. September 4, 2009.
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181505.htm>⁸

Philip's Healthcare's Important Device Safety Alert
http://www.healthcare.philips.com/us_en/support/fetal_monitor_notice.wpd⁹

[Return to Top](#)

[Return to Medsun Home](#)¹⁰

Hospira Issues Urgent Device Recall For AC Power Cords

[Print Item](#)
[E-mail Item](#)

Hospira Press Release

Hospira and FDA notified healthcare professionals and patients of a nationwide recall of devices that have defective AC power cords in response to reports of sparking, charring and fires on the plug of the power cord. Users with affected power cords that have bent or cracked prongs, burnt plastic or excessive wear and tear should discontinue use immediately and contact their Hospira sales representative or Hospira Technical Support Operations.

Additional Information:

Hospira Issues Urgent Device Recall For AC Power Cords. Hospira Press Release.
August 14, 2009.

<http://www.fda.gov/Safety/Recalls/ucm178158.htm>¹¹

[Return to Top](#)

[Return to Medsun Home](#)¹²

**Qualitest Pharmaceuticals, Inc. Issues a Voluntary Nationwide
Recall of Accusure Insulin Syringes [31G, 1/2 cc and 1 cc]** [Print Item](#)
[E-mail Item](#)

FDA MedWatch Safety Alert

Qualitest Pharmaceuticals and FDA notified patients and healthcare professionals of a voluntary nationwide recall of two lots of Accusure Insulin Syringes. The syringes in these lots have been found to have needles which can detach from the syringe. When the needle becomes detached from the syringe during use, it can become stuck in the insulin vial, push back into the syringe, or remain in the skin after an injection.

Additional Information:

FDA MedWatch Safety Alert. Accusure Insulin Syringes [31G, 1/2 cc and 1 cc]. August 21, 2009.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts>¹³

Recall – Firm Press Release. Qualitest Pharmaceuticals, Inc. Issues a Voluntary Nationwide Recall of Accusure® Insulin Syringes [31G, 1/2 cc and 1 cc]. August 21, 2009.

<http://www.fda.gov/Safety/Recalls/ucm179943.htm>¹⁴

[Return to Top](#)

[Return to Medsun Home](#)¹⁵

**Class I recall of Alaris System (Cardinal Health) for various
problems** [Print Item](#)
[E-mail Item](#)

FDA Recall Notice

FDA notified healthcare professionals of the Class 1 recall of various modules of Cardinal Health's Alaris System, electronic infusion pumps that deliver controlled amounts of medications or other fluids to patients through an intravenous, intra-arterial, epidural, and other routes of administration. The firm initiated the recall after identifying five problems that affected the Alaris System, including failure of the occlusion warning message, syringe volume warning message, electrostatic discharge protection circuitry and fluid ingress tubing.

Additional Information:

FDA Recall Notice. Cardinal Health, Various Modules of the Alaris System. August 5, 2009.

<http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm175886.htm>¹⁶

[Return to Top](#)

[Return to Medsun Home](#)¹⁷

GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone) Glucose Monitoring Technology

[Print Item](#)
[E-mail Item](#)

FDA MedWatch Safety Alert

FDA notified healthcare professionals of the possibility of falsely elevated blood glucose results when using GDH-PQQ glucose test strips on patients who are receiving therapeutic products containing certain non-glucose sugars. These sugars can falsely elevate glucose results, which may mask significant hypoglycemia or prompt excessive insulin administration, leading to serious injury or death. The FDA Public Health Notification provides a list of GDH-PQQ Glucose Test Strips and recommends that healthcare practitioners avoid using GDH-PQQ glucose test strips in healthcare facilities or take steps to never use them on patients receiving interfering substances.

Additional Information:

FDA MedWatch Safety Alert. GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone) Glucose Monitoring Technology. August 13, 2009.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm177295.htm>¹⁸

FDA Public Health Notification. FDA Public Health Notification: Potentially Fatal Errors with GDH-PQQ* Glucose Monitoring Technology. August 13, 2009.

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm176992.htm>¹⁹

Advice for Patients: Serious Errors with Certain Blood Glucose Monitoring Test Strips. August 13, 2009.

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PatientAlerts/ucm177189.htm>²⁰

[Return to Top](#)

[Return to Medsun Home](#)²¹

Pump Up the Volume - Tips for Increasing Error Reporting

[Print Item](#)
[E-mail Item](#)

The Institute for Safe Medication Practices (ISMP)

Error-reporting systems represent one of the primary means by which healthcare providers learn about potential risks, actual errors, causes of errors, and error prevention.

Error reporting is a fundamental component of a safety culture, but persuading healthcare workers to submit reports is no easy task given the potential disincentives to reporting. The article lists some best practices that can impact the quantity and quality of reports.

Additional Information:

ISMP Medication Safety Alert! Pump Up the Volume – Tips for Increasing Error Reporting. February 9, 2006.

<http://www.ismp.org/Newsletters/acutecare/articles/20060209.asp>²²

[Return to Top](#)

[Return to Medsun Home](#)²³

LabNet

Novel Influenza A (H1N1) Virus Infections Among Health-Care Personnel

[Print Item](#)
[E-mail Item](#)

CDC MMWR

Soon after identification of novel influenza A (H1N1) virus infections in the United States in mid-April 2009, CDC provided interim recommendations to reduce the risk for transmission in health-care settings. These included recommendations on use of personal protective equipment (PPE), management of health-care personnel (HCP) after unprotected exposures, and instruction of ill HCP not to report to work.

Additional Information:

CDC MMWR. Novel Influenza A (H1N1) Virus Infections Among Health-Care Personnel. June 19, 2009.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5823a2.htm?s_cid=mm5823a2_e²⁴

[Return to Top](#)

[Return to Medsun Home](#)²⁵

Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases

[Print Item](#)
[E-mail Item](#)

CDC MMWR

The recommendations in this report are intended to serve as guidelines for considering and implementing good laboratory practices to improve quality and health-care outcomes related to molecular genetic testing for heritable diseases and conditions and enhance oversight and quality assurance practices for molecular genetic testing under the CLIA regulatory framework.

Additional Information:

CDC MMWR. Good Laboratory Practices for Molecular Genetic Testing for Heritable Diseases. June 12, 2009.

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5806a1.htm?s_cid=rr5806a1_e²⁶

[Return to Top](#)

[Return to Medsun Home](#)²⁷

GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone)

[Print Item](#)

Glucose Monitoring Technology

[E-mail Item](#)

Please see this month's FDA MedWatch Safety Alert which notifies healthcare professionals of the possibility of falsely elevated blood glucose results when using GDH-PQQ glucose test strips on patients who are receiving therapeutic products containing certain non-glucose sugars.

Additional Information:

FDA MedWatch Safety Alert. GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone) Glucose Monitoring Technology. August 13, 2009.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm177295.htm>²⁸

MedSun Newsletter. September 2009. GDH-PQQ (glucose dehydrogenase pyrroloquinoline quinone) Glucose Monitoring Technology.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=40#4>²⁹

[Return to Top](#)

[Return to Medsun Home](#)³⁰

HomeNet

Learning to Use a Home Medical Device: Mediating Age-Related Differences with Training

[Print Item](#)

[E-mail Item](#)

PubMed/National Library of Medicine

The School of Psychology at the Georgia Institute of Technology examined the differential benefits of instructional materials for younger and older adults learning to use a home medical device. The data provide practical information to guide the development of training programs for systems that will be used by both younger and older adults; they also demonstrate the need for age-related usability testing even for training program design.

Additional Information:

PubMed/National Library of Medicine. Learning to Use a Home Medical Device:
Mediating Age-Related Differences with Training. Fall 2002.
<http://www.ncbi.nlm.nih.gov/pubmed/12502154>³¹

[Return to Top](#)

[Return to Medsun Home](#)³²

KidNet

**Stabilet Infant Warmer models 200, 300, 1250, 1500, 200/3000,
2000, 2200/3200, 3000, and 3200 [Draeger/Hill-Rom]** [Print Item](#)
[E-mail Item](#)

FDA MedWatch Safety Alert

FDA notified healthcare professionals of a Class 1 recall of these models of the Stabilet infant warmer because these out-of-date devices may cause serious injury to infants and caregivers due to the possibility that the warmer might be the ignition source for a fire. On July 20, 2009, Draeger sent a recall letter to all known customers, requested customers remove the affected devices from service, remove the heating element and the power cord to make the device unusable once removed from service and emphasized these devices are not to be used, donated or sold for any other purpose. Original safety information updated on August 25, 2009.

Additional Information:

FDA MedWatch Safety Alert. Stabilet Infant Warmer models 200, 300, 1250, 1500, 200/3000, 2000, 2200/3200, 3000, and 3200 [Dräeger/Hill-Rom]. August 25, 2009.
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm173239.htm>³³

Class I Recall Notice - Draeger Medical Inc., Stabilet Infant Warmer. August 25, 2009.
<http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm180073.htm>³⁴

Recall - Firm Press Release. Dräger Initiates a Voluntary Device Recall of Stabilet Contacts Current Users. July 20, 2009.
<http://www.fda.gov/Safety/Recalls/ucm172783.htm>³⁵

[Return to Top](#)

[Return to Medsun Home](#)³⁶

Philips Avalon Fetal Monitors

[Print Item](#)
[E-mail Item](#)

Please see this month's FDA MedWatch Safety Alert which notifies healthcare professionals of inaccurate readings when using Philips Avalon Fetal Monitors, Models FM20, FM30, FM40, and FM50 with the ultrasound transducer.

Additional Information:

FDA MedWatch Safety Alert. Philips Avalon Fetal Monitors. September 4, 2009.
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm181505.htm>³⁷

MedSun Newsletter. September 2009. Philips Avalon Fetal Monitors.
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=40#1>³⁸

[Return to Top](#)

[Return to Medsun Home](#)³⁹

Highlighted MedSun Reports

Highlighted Reports

[Print Item](#)
[E-mail Item](#)

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period June 1 through June 30. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

GENERAL & PLASTIC SURGERY

Device 1:

Type: Laser, Ktp
Manufacturer: American Medical Systems, Inc.
Brand: Aura Xp

Device 2:

Type: Bronchofiberscope
Manufacturer: Olympus America, Inc.
Brand: Bf-p40

Device 3:

Type: Fiber, Laser, 600 Micron
Manufacturer: American Medical Systems, Inc.

Problem:

An adolescent patient was admitted to the hospital with three-month history of persistent pneumonia. CT scan showed calcified mass obstructing the right middle lobe takeoff intraluminally. A surgical procedure was scheduled for direct laryngoscopy, bronchoscopy and biopsy of mass with KTP laser.

Patient was initially intubated and a flexible adult fiber optic bronchoscope was placed through ETT. Biopsies were obtained using a flexible biopsy forceps through the bronchoscope. The KTP laser was used to control bleeding. The patient had initially been ventilated with 21% FiO₂ at the start of the case, but with continued desaturations secondary to airway leak around the bronchoscope, the FiO₂ was increased to 100%. The surgeon was unable to remove the mass so the flexible bronchoscope was removed.

A rigid bronchoscope was then placed and attempts to remove the mass were unsuccessful. Rigid bronchoscope was removed and patient was reintubated. Several more specimens were obtained using the flexible bronchoscope through the ETT. Bleeding was stopped using the KTP laser. Attempts were also made to ablate the mass with the KTP.

A general surgeon was called to discuss the possibility of a transthoracic approach to remove the mass. The primary surgeon used the KTP to demonstrate to the general surgeon the hardness of the mass. As the laser was engaged the light of the bronchoscope went off. The laser was put on standby and the bronchoscope removed. Patient was extubated, oxygen turned off, anesthesia circuit disconnected and changed, patient masked and then reintubated. A small amount of smoke was noted in the ETT that was removed. Upon examination of the bronchoscope, it appeared as though one side of the scope had been melted.

This examination revealed evidence of melted plastic verses vaporized plastic from the end of the flexible bronchoscope. The patient was transferred from the operating room to the Pediatric Intensive Care Unit. The patient remained intubated until 2 days after the procedure, when she was successfully extubated. The patient remains hospitalized and is scheduled to return to the operating room for removal of the mass.

Device:

Type: Suture, Vicryl Coated

Manufacturer: Ethicon, Inc.

Brand: Vicryl

Model #: J544P31

Lot #: BC6625

Cat #: J544

Problem:

While suturing the eye muscle, the 6-0 Vicryl suture started to fray as it was being pulled through the eye muscle. Suture was replaced with the same lot# and surgery was

completed without further suture problem.

Device:

Type: Retractor, Illuminated, Surgical
Manufacturer: Electro Surgical Instrument Company
Brand: Lighted Retractor
Cat #: 08-0195G

Problem:

An illuminated retractor was connected to 300W light source. Patient burned from hot retractor. Patient sustained 3rd degree burns. Manufacturer states to use 150W maximum light source on labeling. However, once the device is sterilized and repackaged, it no longer retains the manufacturer's label. OR management is planning on creating their own labeling for the new packaging and light sources to include 150W maximum light source recommendation.

Device:

Type: Snare, Surgical, Ivc Filter
Manufacturer: Bard Peripheral Vascular, Inc
Brand: Recovery Cone Removal System
Model #: FBRC G2X
Lot #: GFTD1559

Problem:

During removal of an IVC filter the radiopaque marker on the IVC retrieval catheter loosened. When the IVC filter and retriever was removed from the right IJ incision site, the 4mm marker ring dislodged and remained just below the skin.

Device 1:

Type: Trocar
Manufacturer: Applied Medical Resources Corp.
Brand: Optical Separator System
Model #: C0152
Lot #: 1079076
Other #: +H699C015210H

Device 2:

Type: Trocar
Manufacturer: Applied Medical Resources Corp.
Brand: Optical Separator System
Model #: C0116

Lot #: 1080786
Other #: +H699C011610H

Device 3:

Type: Trocar
Manufacturer: Applied Medical Resources Corp.
Brand: Optical Separator System
Model #: C0116
Lot #: 1079080

Problem:

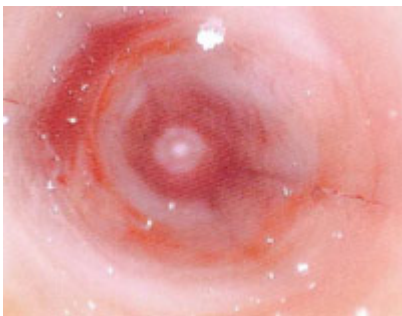
A physician was placing the initial trocar, model C0152, during a laparoscopic procedure, when he noticed through the camera, a white particle inside the distal tip of the obturator. The scope and inner trocar were pulled out. The scope was cleaned before proceeding. The white particle was inside the obturator and did not enter the patient.

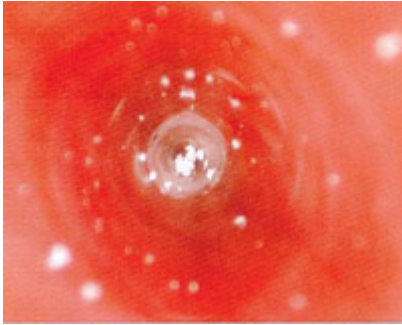
Similar incidents happened during surgeries a few days previous and on one approximately a month earlier.

In the surgery a few days earlier, the physician was placing the initial trocar, model C0116, during laparoscopy, when he noticed multiple white particles falling into the distal tip of the obturator. Particles collected inside the tip. This was seen through the camera and a photo was taken showing multiple white particles. The trocar and scope were removed to prevent particles from entering patient.

Also, during a case approximately a month earlier, the physician was placing a disposable trocar, model C0116, during a laparoscopic procedure. He noticed multiple white particles falling into the distal tip of the obturator. The white particles collected in the distal tip of the obturator. A photo was taken showing multiple small white particles. The obturator and scope were withdrawn. No particles entered the patient. A different scope was used to proceed with the procedure.

See device images





CARDIOVASCULAR

Device 1:

Type: Pump, Cardiovascular, Roller
Manufacturer: Sorin Group USA, Inc.
Brand: Stockert Slii Encore Pump Module
Model #: S3
Cat #: 10-60-00

Device 2:

Type: Tubing, Bypass, Ecmo
Manufacturer: Medtronic Inc.
Brand: Intercept Custom Tubing Pack
Cat #: 2A95R10

Problem:

ECMO was activated for a patient who had a cardiac arrest and was receiving CPR. While the ECMO circuit was being set up, the ECMO circuit was placed into the roller head of the pump incorrectly. The circuit was placed in the pump raceway backwards which caused the circuit to fill with air. The circuit was clamped, the problem identified and the circuit was de-aired. Estimated length of time from until issue was identified was about 5-6 minutes. This incident occurred prior to being used on the patient. The user was very familiar with the device. We have not seen this occur previously at our facility. We are currently taking steps to prevent this from happening in the future such as labeling the tubing, and the pump with directional arrows as well as doing a time out to check the tubing for proper placement. We suggest that there should be a better manufacturer design, such as color coding the lines with red for arterial and blue for venous. Additionally, more information is needed to guide the user in the correct circuit placement. The tubing does not currently come with instructions for loading the pump.

Device 1:

Type: Ventricular Assist Device, Power Unit
Manufacturer: Thoratec Corporation
Brand: Heartmate Ii Power Base Unit

Device 2:

Type: Ventricular Assist Device, Power Unit

Manufacturer: Thoratec Corporation

Brand: Heartmate Ii Power Base Unit

Device 3:

Type: Ventricular Assist Device, Power Unit

Manufacturer: Thoratec Corporation

Brand: Heartmate Ii Power Base Unit

Device 4:

Type: Ventricular Assist Device, Power Unit

Manufacturer: Thoratec Corporation

Brand: Heartmate Ii Power Base Unit

Device 5:

Type: Ventricular Assist Device, Power Unit

Manufacturer: Thoratec Corporation

Brand: Heartmate Ii Power Base Unit

Device 6:

Type: Ventricular Assist Device, Power Unit

Manufacturer: Thoratec Corporation

Brand: Heartmate Ii Power Base Unit

Problem:

Thoratec Heart Mate II (PBU) swapped at patient home to have routine maintenance performed. Hospital Product technician observed a disconnected back-up battery on the unit. After the initial discovery, 5 other units were found to have the same problem. Process for set-up: Hospital orders PBU from Thoratec, who then ships it to us (battery cord typically tucked behind circuit board during shipping), we contact Thoratec's contracted company, who then does the installation of the PBU prior to patient set-up. No back-up power supply in the event of a power failure, would leave patient with no power to the LVAD device which could lead to death or serious injury.

Device:

Type: Defibrillator, External

Manufacturer: Medtronic Inc., Medtronic Emergency Response Systems

Brand: Lifepak 12 3DBiphasic

Model #: LifePak 12

Problem:

The patient was in full arrest and CPR was in progress. The patient was shocked (defibrillated) X 2. The staff charged the machine to 200J, but the defibrillator failed to deliver the shock. This was attempted X 3. The red service light appeared as well as error code D00D. The staff turned the machine off, then back on, recharged it and was able to deliver shock. The patient continued in full arrest with asystole and was pronounced 9 minutes later.

Device 1:

Type: Catheter, Electrode Recording
Manufacturer: St. Jude Medical
Brand: Livewire Steerable, Duo-deca
Model #: 401904 20
Lot #: 2767420

Device 2:

Type: Catheter, Electrode Recording
Manufacturer: St. Jude Medical
Brand: Livewire Steerable, Duo-deca
Model #: 401904 20
Lot #: 2767420

Device 3:

Type: Catheter, Electrode Recording
Manufacturer: Ascent Healthcare Solutions
Brand: Livewire Steerable, Duo-deca
Model #: 401904

Problem:

The physician opened a new steerable electrode diagnostic cardiac EP catheter. The catheter was then introduced to the right atrium via the right femoral vein and inferior vena cava. When the catheter was attached to electrical recording equipment it was found to have a faulty electrode pair. The catheter was removed from the patient and a second new catheter was introduced into the patient. This catheter also had a non-functioning electrode pair and was removed. These catheters have the same lot numbers. A third catheter, which had been reprocessed was opened and was found to have a structural abnormality. These reprocessed catheters are to be tested by Ascent prior to returning the catheter for use. This catheter was not placed in the patient but was bagged to be replaced. A fourth catheter (another new catheter) was opened and was utilized without incident. The case was completed successfully.

Device:

Type: Monitor, Physiologic
Manufacturer: GE Healthcare
Brand: Solar 9500
Model #: Solar 9500

Problem:

Patient was induced and shortly after, the sternotomy a "lead fail message" was displayed on the monitor as one of the ECG leads (lead V) disappeared. The monitor was adjusted to display two of the limb leads (lead II & lead III) instead. All of the ECG leads and electrodes had been carefully placed and covered, so it was considered unlikely that a pad (electrode) had come loose. The cable connection near the patient was also checked. The CVP pressure tracing at the same time was noted to exhibit significant noise artifact and this did not improve after replacing the pressure cable. A few minutes later, it was observed that the arterial line tracing would disappear suddenly from the screen without anyone disturbing or changing anything. Then the arterial line tracing would reappear. This did not improve after changing the pressure cable several times and changing the transducer, so it was assumed that the problem was with the physiologic monitor. In view of the fact that the monitor was critical to the surgical procedure, it was opted to use a transport monitor to display the patient's physiologic information.

Device:

Type: Catheter, Peripheral Dilation
Manufacturer: Abbott Vascular Devices
Brand: Viatrac14 Plus
Lot #: 8080651
Cat #: 1008201-20

Problem:

Balloon burst when expanded to 26 atmospheres. Catheter pulled out of body and balloon dislodged off wire and was found under fluoro to be in iliac. Retrieval device used to retrieve balloon. Manufacturer's recommendation is not to go above 14 atmospheres for the rate of burst.

Device:

Type: Catheter, Snare
Manufacturer: EV3 Inc.
Brand: Snare Replacement Catheter
Lot #: 6227491
Cat #: MC4000
Other #: 4 FR 102 cm

Problem:

#4 French end hole snare catheter advanced into the proximal aspect of left SVC following which an attempt at removing the existing guide wire was unsuccessful due to small caliber of the vessel. Catheter then withdrawn with minimal difficulty, although platinum marker remained within the vessel for unknown reasons. Target vessel was inadvertently embolized with marker. Post angiography demonstrated successful occlusion of target vessel with marker. Position unchanged. No apparent patient injury

Device:

Type: Defibrillator, External
Manufacturer: ZOLL Medical Corporation
Brand: MSeries Cct
Model #: CCT

Problem:

A staff member was retrieving a Zoll CCT defibrillator to use for a transport when the handle snapped away from the defibrillator. This caused the defibrillator to fall and strike the caregiver in the upper leg. The handle broke on both pivot hinges completely separating from the defibrillator. The staff member complained of pain and bruising but did not want to pursue medical intervention. The defibrillator was removed from service for Biomedical evaluation and analysis. This is the third incident of these carrying handles breaking away from this model of defibrillator and the second MedSun report from this facility. The weight of the defibrillator with the battery is approximately 16 pounds.

Manufacturer response (as per reporter) for Defibrillator Monitor, Critical Care, Zoll CCT

Manufacturer requesting that handle assembly be sent back to them for analysis. A replacement handle was sent from Zoll.

See device images





41



42

Device:

Type: Vascular Closure Device

Manufacturer: Abbott Vascular Devices

Brand: Starclose

Lot #: 740266 H

Problem:

After sheath was changed to StarClose sheath, device was inserted through sheath. It was properly snapped to sheath and raised up to begin splitting, but splitting did not work. It was then noticed that a leaflet on the end of StarClose was kinked and would not advance any further. After several attempts at pulling out system with no success, emergency release button was used and StarClose was aborted.

Manufacturer response: the device will be replaced

GENERAL HOSPITAL

Device:

Type: Infusion Pump

Manufacturer: Smiths Medical MD, Inc.

Brand: Medfusion 3500 Syringe Pump

Model #: 3500

Problem:

When nurse was trying to program a drug bolus, she typed in a "2" and the screen displayed a "5." If she typed a "1," it displayed a "4" on the screen. Then, the pump started failing to recognize the type of syringe we utilize.

The pump was taken out of service. There was no harm to the patient.

An in-house safety inspection was completed on this pump. It was found to have a non-functional keypad assembly. The cause of the problem is unknown outside of "general use." It should be noted that this unit was not part of the recent safety recall for keypad replacement, nor did it have the faulty part within it as indicated in the safety recall. The unit's keypad and topcase, as one unit, were replaced. All functional testing was completed yielding values that were within the acceptable range.

Device:

Type: Pre-filled Syringe
Manufacturer: Sanofi-Aventis
Brand: Lovenox
Lot #: 19391

Problem:

Nurse injected prefilled syringe of Lovenox to patient, enabled the safety device which failed and the needle fell out of the syringe and to the floor. The nurse picked the needle up off the floor and as was placing it in the sharps container it slipped and stuck the nurse through the glove on the left thumb. Blood did seep from the site.

Nurse was seen in the ER, baseline HIV, Hep C and Hep B labs were drawn on the source patient and the employee.

Additional information obtained from the site:

It was injected subcutaneously. There was an audible click, the nurse said it was like it over activated and then fell apart.

Device 1:

Type: Enteral Feeding Set
Manufacturer: Covidien Kendall
Brand: Kangaroo Joey
Cat #: 772055

Device 2:

Type: Enteral Feeding Pump
Manufacturer: Covidien Kendall
Brand: Kangaroo Joey

Problem:

Feeding pump was delivering up to 30% more milk than specified. Two incident reports were filed and Clinical Engineering found the problem to be a bad batch of feeding bags (disposables). We were able to replace all bags at our hospitals and we will be checking the new lots prior to use.

We informed the manufacturer of our problem and they provided us with new bags. They were not aware of this issue prior to us informing them of it.

Device:

Type: Syringe Pump

Manufacturer: Smiths Medical MD, Inc.

Brand: Medfusion 2001

Model #: 2001

Problem:

The syringe pump had not delivered any dopamine after running for 3 hours. Further investigation indicated that the syringe drive on this pump had sustained physical damage from being dropped or struck. The damage was visible on the syringe pump's housing. The impact from being dropped or struck damaged the drive mechanism and cracked the housing.

Device:

Type: Iv Infusion Needleless Access Device

Manufacturer: Becton Dickinson

Brand: Interlink Threaded Lock Cannula

Model #: 303369

Cat #: 303369

Problem:

A nurse was changing lines on a vasoactive infusion. She was using a needleless access device used by the hospital. After making the change, the patient was noted to have a precipitous drop in blood pressure and heart rate despite a seemingly uneventful change. The nurse then noted that there was leaking at the site of the needleless access. Upon further investigation, she found that the access device, while appearing intact and screwing on to the needleless port, was actually broken off and never made access to the needleless cap. Thus, the patient was not receiving any of the medication.

Device:

Type: Hospital Bed

Manufacturer: Hill Rom Company, Inc.

Brand: Total Care General Care

Model #: TOTALCARE GC

Problem:

A loud clatter was heard, and a male voice shouting. Staff went to check it out. The tech, (confirmed by patient and family), stated that the patient was using the side rail as support to get up, and it gave out. He jerked to the side, but didn't fall. He complained of pulling and severe pain. Nurse Practitioner and Biomedical engineering was notified. We received order for STAT morphine, which relieved most of the pain (from 8/10 down to 2/10), and patient was taken for STAT lumbar CT (which he was already scheduled for).

Manufacturer response (as per reporter) for Regular hospital bed, Total Care General Care

The "false latching" concern of the site, was duplicated by slowly & gently raising the siderail and holding it up just before the latch makes full engagement onto latch-pin. The "false latch" is defined as, "A siderail remaining in the up position without being fully latched and not capable of supporting the full design load."

Device:

Type: Needle, Hypodermic, Single Lumen

Manufacturer: Smiths Medical

Brand: Gripper Plus

Lot #: 078X39

Cat #: 21-2767-24

Other #: Non-coring (Huber) safety needle

Problem:

Nurse was removing Huber needle from implanted port. Safety device did not engage in locked safety position - needle came up further than it should have. Neither patient nor nurse sustained injury from malfunction.

Additional information obtained from the site:

There is no patient information and it has no bearing on the incident. It has happened a few times in the past year or so - I may have submitted previous reports on it. All users are oriented to proper use of the device.

This device been in use in our facility at least 5 years (probably longer) and there has not been any design changes to the device.

The person removing the needle was a staff nurse in our ambulatory clinic. They are trained by the educator and their preceptor during new hire orientation to use it properly. The patient/family had nothing to do with managing the device.

Device:

Type: Enteral Feeding Pump

Manufacturer: Moog Medical Devices Group (Zevex)

Brand: Entralite Infinity

Problem:

Patient's mother set the pump for an overnight feeding. She checked the patient at 6 am and found the bag was empty and the device continued to pump air into the infant. The patient's mother vented the patient (released the air in the child's abdomen via G-tube) and observed no harm or discomfort. Another pump was sent out and the malfunctioning pump was shipped back to Moog for testing.

This is one of six events our facility is aware of that involve improper administration of tube feeds by this make and model of pump. The pump either delivered product too early or too late (by hours at a time) in vulnerable populations.

Our facility has discussed this problem with the manufacturer, and they have stated in previous reported cases that they could not identify a problem with the product. However, the problem continues with this type of pump. In addition, most cases involve "highly viscous" feeds. The manufacturer used water to test the pumps, and this may have contributed to a false negative with regard to product defects.

ANESTHESIOLOGY**Device:**

Type: Air/ O2 Blender

Manufacturer: Cardinal Health/Bird

Brand: 3800 Microblender

Model #: 3800A

Problem:

The medical air supply was connected to the medical air input on the blender and the oxygen supply was connected to the primary output not the oxygen input. The blender was set to deliver 21% oxygen but when the auxiliary outlet oxygen concentration was tested it was 100%. A flow meter was connected to the auxiliary output. The flowmeter was delivering blended gas to the baby via a nasal cannula.

OBSTETRICS/GYNECOLOGY**Device:**

Type: Catheter, Balloon, Transcervical

Manufacturer: Gynecare Worldwide

Brand: Thermachoice Iii
Lot #: BCMG05

Problem:

Uterine balloon therapy had been in progress for approximately four minutes (out of eight total) when the machine recorded heating error 6506. The manufacturer rep was present in the OR suite at this time. The procedure was stopped and the device was removed, a small defect was noted in the balloon. A second balloon was then inserted and the same problem was reported six minutes into the procedure with same error message. The procedure was stopped at this point and the device removed. The physician was satisfied; the goal of the procedure had been achieved and the patient withstood the procedure with no adverse outcome.

Device:

Type: Manipulator, Uterine
Manufacturer: Cooper Surgical
Brand: Rumi System
Model #: UMB678
Lot #: 45169

Problem:

Patient undergoing laparoscopic lysis of pelvic adhesions when the Rumi uterine manipulator, the surgeon was using, somehow lacerated a part of the pt's cervix. Apparently, the surgeon noted vaginal bleeding so the edges of the cervix were grasped and examined. The surgeon identified a cervical laceration for which she placed some sutures to stop the bleeding. The bleeding did not stop, so the surgeon utilized a cystoscope which allowed visualization of 2 additional areas of bleeding which was cauterized to stop the bleeding. Patients' procedure was completed and patient was taken to recovery. After procedure, surgeon visually examined the device and noticed a 2mm barbed area of irregular material which she feels may have produced traumatic injury to pt's cervix.

Device:

Type: Birthing Bed
Manufacturer: Hill-Rom Company, Inc
Brand: Affinity
Model #: Affinity 4

Problem:

Visitor sat on end of bed. When he stood up, the bottom half of the bed fell to the floor. The rest of the bed dropped into reverse trendelenburg. Two bolts and a bracket were

found under the foot of the bed. Patient and visitor were unharmed. Patient weight-166 lbs. Visitor weight unknown. During repair of bed it was noted that 12 other beds in our system had the same loose bolt and were at risk of collapse. The Hill-Rom service repairman stated that it was a common problem.

Manufacturer response (as per reporter) for Birthing bed, Affinity:

It is a problem that has been seen frequently at other locations as well. Our site had a total of 26 affected beds that had to be repaired in the same way. Bolts were loose and had to be replaced.

Device:

Type: Female Surgical Contraception

Manufacturer: Cooper Surgical

Brand: The Filshie Clip

Lot #: 20561

Cat #: AVM851

Other #: FE0105

Problem:

Reported unintended pregnancies (4) from patients and physicians who underwent a tubal ligation procedure during a 13 month period. The filshie clips used in the procedures were from the same lot number.

CLINICAL CHEMISTRY

Device:

Type: Calibrator

Manufacturer: Bio-Rad Laboratories, Inc.

Brand: Anti-borrelia (Lyme) Eia

Lot #: 082132

Cat #: 503231

Problem:

While analyzing the data from a recent run of specimens, the technician noticed that the positive control was not as high as expected, but still within acceptable range. During the investigation of this, BioRad was contacted. It was discovered a "scaling factor" should have been entered into the instrument for this test with each run. Scaling factor not printed on calibrator so technician did not know to enter it. The scaling factor is supposed to be printed on the vial when required for a procedure. The vial did not contain the factor label. Nine patients had lab results reported to them that were incorrect. The patients will have to come in for a second test.

Device:

Type: Chemistry Analyzer
Manufacturer: Siemens Medical Solutions Diagnostics
Brand: Dade RxI
Model #: DADE DIMENSION RXL
Lot #: BC0069
Cat #: RF421C

Problem:

ER physician called and notified the lab director that he thought we were having trouble with our troponins. Troponin I results were falsely elevated, resulting in a patient being transferred from our facility to another for cardiac catheterization. Upon arrival at other facility, Troponin I performed with a negative result being obtained. Cardiac catheterization not performed. During the resolution process, we discovered a precision problem with the instrumentation and had the instrument decontaminated. Recalibration of the assay was performed and quality control was acceptable. No shifts in quality control were noted prior to notification of a suspected problem by the ER physician. Patients were repeated on alternate analyzer and amended reports were issued. Troponin I testing was discontinued on patients until problem was resolved.

Device:

Type: Glucometer
Manufacturer: Roche Diagnostics Corporation
Brand: Accu-chek Inform
Model #: Accu-Chek

Problem:

Nursing dropped the glucometer and broke it. The glucometer was taped together with scotch tape and ran for patient results. Nurse obtained a critical value and treated patient with insulin. At change of shift, the new nurse noted patient was cold and unresponsive. The patient had a blood sugar of 15. Glucose performed in the laboratory. No documentation of controls being performed after the meter was broken. Other patients were tested, but values obtained were within normal ranges. Patients were retested by oncoming shift with a different meter.

PATHOLOGY**Device:**

Type: Powder/reagent
Manufacturer: SIGMA-ALDRICH

Brand: Sigma Hyaluronidase Powder

Problem:

Hyaluronidase powder from Sigma was contaminated with yeast. Order#=H3506-5G, lot#=029K7001. Bottle was opened. A second bottle also showed contamination. We had two joint fluids that had yeast reported from the cytospin slide; however, cultures were negative. Cytospins were then performed using (1) sterile saline & (2) sterile saline mixed with hyaluronidase confirming the contamination.

Sigma does not claim sterility of this product. We have not had any previous problems with this product. Company has recently switched packaging from glass to plastic bottles. Company is investigating.

EAR, NOSE & THROAT

Device:

Type: Cochlear Implant

Manufacturer: Cochlear Americas

Brand: Nucleus Freedom

Model #: Nucleus Contour device

Problem:

Patient with a history of traumatic brain injury and hearing loss status post his trauma. He had minor benefit after cochlear implantation and the implant was found to have defective electrodes.

GASTROENTEROLOGY & UROLOGY

Device:

Type: Lithotripter, Ultrasonic

Manufacturer: Medispec LTD

Brand: Lithotripsy Unit Sw-7 Medspec

Model #: 16-230A

Problem:

Extracorporeal Shock Wave Lithotripsy (ESWAL) malfunctioned. Troubleshooting done by staff and BioMed. Lithotriper misfired. Staff removed spark plug; no damage. Changed water. Within ten shots, the malfunction happened again. Call Medispec, and trigger changed for ECG to SLOW. Problem still existed. KV output to 15. Misfired, but not at the same frequency. MD was able to get through the case.

The rep from Medispec came in to complete repair. He replaced the high voltage generator. It should be replaced every 1 million shots. Meter read 1,699,000 and was overdue. He also replaced the membrane. Now fully operational.

Device:

Type: Hemodialysis Machine

Manufacturer: Gambro Renal Products, Inc.

Brand: Phoenix

Model #: Phoenix

Problem:

Bicart motor mounts failed and caused the motor to bind and not pump properly.

Device:

Type: Duodenoscope

Manufacturer: Olympus America, Inc.

Model #: TJF 160VF

Other #: Cook Stent #SPSOF-5-2.5

Problem:

An ERCP was being performed. Multiple products were introduced into the scope. Then a balloon was introduced and a pancreatic stent was pushed out of the scope. The stent was lodged in the scope from a previous patient. The stent entered the current patient's duodenum only and was retrieved immediately.

Device:

Type: Endoscopic, Biopsy Port Cap

Manufacturer: Boston Scientific Corporation

Brand: Microvasive Rx Biliary System Locking Device And Biopsy Cap

Lot #: 12369655

Cat #: 4526

Problem:

Item periodically used during ERCP procedure. It is a disposable biopsy port cap with sponge disc inside that endoscopic accessories pass through. This incident is the second time in recent weeks that the sponge disc has been pushed into endoscope working channel - requiring significant effort and time to remove.

Concerns are:

1. No foreign body should remain inside scope - inhibits further use of working channel during that case and follow-up reprocessing.

2. Infection control risk if disc should remain behind.
3. Risk for scope injury with effort required to dislodge.
4. Scope out of circulation and unavailable for clinical use.

Manufacturer has communicated with the site that they are investigating.

NEUROLOGY

Device:

Type: Ventricular Catheter

Manufacturer: Medtronic Neurologic Technologies

Brand: Bioglide

Cat #: 27782B

Problem:

A Medtronic Bioglide VP shunt malfunction was retrospectively identified. The patient had come in ~8 months ago for a shunt malfunction. Since then, our facility had sent out a recall letter to the patient, alerting them that the manufacturer had initiated a device recall. The patient's mother believed that the shunt malfunction that occurred was related to the disconnection problem identified in the recall. Upon reviewing the operative report, this was confirmed. Per the operative notes:

The patient was brought to the operating room. We went to remove the reservoir snap assembly and it was apparent that the shunt had broken off at the attachment of the ventricular catheter to the reservoir dome and the catheter was lodged in the brain. At this point, we tested the distal shunt runoff and found there was no runoff. Therefore, we opened up the abdominal incision and began the process of finding the proximal ventricular catheter. Had to widen the bone opening around the area of the shunt insertion site, dissect down through the brain parenchyma approximately 1cm into the parenchyma until the distal ventricular catheter could be found. It was removed without difficulty.

Please see two recalls online available at:

<http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm126620.htm>

and

http://wwwp.medtronic.com/Newsroom/NewsReleaseDetails.do?itemId=1238091091955&lang=en_US

Device:

Type: System, Hypothermia, Intravenous, Cooling

Manufacturer: INNERCOOL therapies

Brand: Rapidblue

Lot #: 8197-0011

Cat #: RapidBlue

Problem:

The Innercool on-call representative was contacted by the ICU nurse because the Rapid Blue machine was re-warming the patient too quickly. The Innercool folks say that it was determined that initially, the patient was being warmed at the MAX rate, rather than 0.2 degC/hr. MAX is the default setting. In attempting to correct this problem, the rep also instructed the RN to turn off and re-start the machine. When this was done, the "Accutrol" mode was inadvertently accepted as the catheter type on the start up menu. We only use "Standard" catheters, not "Accutrol", but Accutrol is the default setting. This resulted in a malfunction error alarm that is only related to the Accutrol mode. It is unclear exactly when and if they figured out that the setting was wrong, and when and if they figured out that this was the cause of subsequent malfunction error messages. Once this alarm had been triggered, the rep and RN agreed to switch back to the old console to avoid further frustration and alarms. The patient achieved stable condition.

Our facility is now putting a note on the new console reminding staff not to rewarm at the max rate and not to use the accutrol setting. We have informed the company that changing the default setting is necessary for our facility to accept the new console.

In our discussions with the company, we learned they had identified the following:

This particular error has been identified as a software anomaly that surfaced during beta-site testing of the console in the Accutrol mode. The error is cleared by shutting down and re-starting the machine. It is not a consistent issue and only surfaces once in a while. In any event, a software fix was identified and a revision was implemented just a few weeks ago in all units being tested at "Accutrol" sites.

PHYSICAL MEDICINE

Device:

Type: Stimulator, Muscle, Powered
Manufacturer: Chattanooga Group Inc
Brand: Forte
Model #: FORTE 400 Combo

Problem:

Patient received electrical stimulation to right shoulder. Shortly after application, he reported it was "hot." Device was turned down to comfort level.

Device:

Type: Hip And Knee Arthroplasty Table

Manufacturer: Mizuhosi
Brand: Hana
Model #: 6875
Cat #: #6875

Problem:

The "fracture table" or Arthroplasty table is shaped like an ironing board. The patient's head is at the wide end with the hips at the pointed end. A perineal post is inserted between the legs to prevent the patient from rolling. There is also an abdominal safety strap. The legs are placed in boots with traction applied, and are unsupported from below. This allows the legs to move on pivots to give greater surgical access and improve limb positioning. The patient was 80 Kg. A sheet was placed beneath the patient at the beginning of the procedure to help with transfer back onto a stretcher for extubation at the end of the case. (The table is considered unsafe for intubation and extubation should emergency procedures arise). The perineal post was removed. The feet were removed from the boots and were being held by the surgeon. The anesthesiologist was holding the sheet at the head of the table. There was an RN on each side of the patient. An RN removed the abdominal strap, and turned momentarily to pull the stretcher (which was right beside her) up against the table. When the RN turned and took her hand away from the patient he began to slide to the floor. The weight of his hips was displaced to one side of the point in the table. Because three people were still holding the patient when the 4th RN turned quickly, the patient had a controlled fall/slide to the floor.

The table does not have adequate support or features to ensure safe transfer of patients to a stretcher. The transfer board offered by the manufacturer is difficult to use and has limited instructions for use that do not seem to cover all instances of transfer.

Manufacturer response (as per reporter) for Hana Hip and Knee Arthroplasty table, the manufacturer rep is coming to evaluate the product with us and attend a staff in-service.

ORTHOPEDIC

Device:

Type: Reamer, Orthopedic
Manufacturer: Stryker Orthopaedics
Brand: Bixcut Fixed Head -Modified Trinkle Fitting
Lot #: 0123K754848
Cat #: 0227-6100

Problem:

Stryker reamer Size 10 uncoiled while surgeon was reaming bone. Surgeon stopped surgery to remove all pieces of reamer.

See device image



43

Device:

Type: Cannula Delivery System For Cement

Manufacturer: Jupiter Surgical Systems

Brand: Jupiter Low Pressure Delivery System

Other #: Item # JS-LPSDS-01

Problem:

Physician performed a vertebroplasty on thoracic eight and thoracic nine. The physician used the Jupiter Low Pressure Delivery system to gain access and deliver the cement to the proper vertebral body. Upon completion of the case it was noted on the C-arm image that the tip to one of the cannulas was missing. These tips are not supposed to be able to come off. However, the tip broke off in the patient. The patient's incision was already closed and the surgeon had left the room. The patient was still intubated and on the surgery bed. The surgeon was notified immediately and returned to the surgery room. Physician reopened the incision to remove the tip. There was minor harm to the patient.

RADIOLOGY

Device:

Type: X-ray System, Cath/angio

Manufacturer: Siemens Medical Solutions USA, Inc.

Brand: Mpu

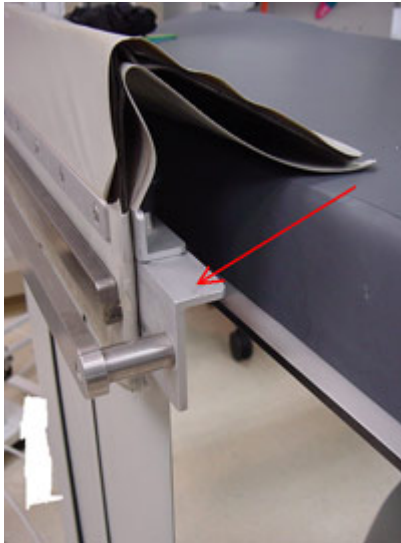
Model #: 05904433

Problem:

An injury was noticed by a patient care tech assistant. This was noticed after the procedure. There was blood on the blanket. Initially we thought that the IV pulled out after we moved the patient from exam table to stretcher. Examination of the right hand showed about a 1x1 cm skin break/abrasion on the center back of right hand which might have been caused by moving the patient. The hand may have gotten caught in the gap between the table and stretcher. The side bar of the X-ray exam table has a sharp corner.

Usually we cover it with a blanket to prevent such an injury.

See device images



[Return to Top](#)

[Return to Medsun Home](#)⁴⁴

Medical Device Problem Summaries

Summary of MedSun Reports Describing Adverse Events With Point-of-Care (POC) Glucose Meters

[Print Item](#)
[E-mail Item](#)

By Ahmed Haque, Patient Safety Staff, 2009

Point-of-Care (POC) glucose meters are medical devices intended to approximately

evaluate the glucose concentrations found in blood. These devices are intensively used by patients with diabetes mellitus, who must carefully monitor their glucose readings to prevent entering hyperglycemia or hypoglycemia. Unlike their laboratory counterparts, POC meters can rapidly deliver results, often within seconds. Whole blood samples are obtained by pricking the skin with a lancet and then placing the resulting drop on a disposable strip. The various reagents, found in the strip and device, react with the glucose allowing a measurement to be made. Some meters measure the amount of electricity that can pass through sample; others measure how much light reflects from it. These measurements can then be converted into a digital output of glucose concentration (1,2).

Over the past five years, MedSun has received 24 adverse event reports associated with POC blood glucose meters. The reports represent seven manufacturers: Roche Diagnostics (14), Lifescan Inc (5), Abbott Diabetes Care Inc (3), Medtronic Minimed (1), and Becton Dickinson (1). These reports were submitted between January, 2004 and July, 2009.

The reported device problems include:

- Discrepancy with lab result (14)
- Inconsistent results using same device (3)
- Missing/defective device components (3)
- Defective strips (1)
- Time stamp error (1)
- Needle break (1)
- Test control solution fails quality control (1)
- Barcode identification error (1)
- Device failure after being dropped (1)

During this time period there were no reported deaths associated with these devices. Hospitalizations due to incorrect readings were reportedly required in two of the events. In 10 of the reports, clinicians found the reading of the device to be too high; in 4 of the reports they found the readings to be too low. There were also 2 reports of needle related injuries involved with the finger prick.

Of the reports that listed patient age, 2 listed patients aged 21 and younger and 17 listed patients aged over 21. Of the reports that listed gender, 14 involved female patients and 6 involved male patients.

These MedSun reports contributed to FDA awareness of the device problems. FDA follow-up with the manufacturer may have contributed to the following recalls.

Recall Information						
Recall Number	Trade Name/Produ	Recall I	Date Initiated	Date Posted	Recalling Manufactur	Reason for Recall

r	ct	Class			er	
Z-1070-2009	OneTouch SureStep Test Strips	2	11/25/2008	3/17/2009	Lifescan Inc	Deformity in the test strip may result in insufficient blood transfer to reaction area, resulting in inaccurate test results.
Z-1317-2008	OneTouch Data Management Software v1.0	3	12/18/2007	4/8/2008	Lifescan Inc	Meter Temporarily Freezes-- A software compatibility issue may cause the blood glucose meter to cease operations and freeze temporarily.
Z-0112-2008	Multiple brand names including: Precision Xtra	2	8/2/2007	2/14/2008	Abbott Diabetes Care Inc.	Damage could lead to no display. Meters manufactured after January 31 2007 could exhibit meter display damage if dropped on a hard surface. These meters could exhibit unreadable lot number fields and date/time fields in addition to complete blanking of the numerical reading portion of the display.

Z-0458-2008	Advance Micro-draw Blood Glucose Monitoring System	3	10/18/2007	12/13/2007	ARKRAY USA INC.	Mislabeled/coded strips : Meter kits from this lot contain mislabeled 10-count test strip vials. The code number printed on the Advance Micro-draw 10-count test strip bottle is incorrect. The code number on the vial is 867 when it should be 687. The 687-labeled code chip contains the correct calibration information for the 867 test strips so the meter will function properly and give accurate
Z-0264-2007	One Touch Ultra	1	11/1/2006	12/29/2006	Royal Global Wholesale	Counterfeit Glucose Test Strips
Z-0265-2007	One Touch Basic/Profile	1	11/1/2006	12/29/2006	Royal Global Wholesale	Counterfeit Glucose Test Strips (manufacturer unknown)
Z-1307-06	FreeStyle Flash	2	5/22/2006	8/3/2006	Abbott Diabetes Care Inc.	The products may encounter display problem 'Er 4' message during prolonged use when the low battery symbol

						is displayed. The situation can render the meter either inoperable or operable with invalid user configuration data including selectable unit of measure and strip calibration code.
Z-1306-06	FreeStyle	2	5/22/2006	8/3/2006	Abbott Diabetes Care Inc.	The products may encounter display problem 'Er 4' message during prolonged use when the low battery symbol is displayed. The situation can render the meter either inoperable or operable with invalid user configuration data including selectable unit of measure and strip calibration code.
Z-0887-05	LifeScan	2	11/17/2003	6/14/2005	Lifescan Inc	A Control Solution range for the OneTouch Ultra Test Strip of 111-150 mg/dL was incorrectly labeled as 97-131 mg/dL.
Z-0821-	LifeScan	1	4/11/2005	5/17/2005	Lifescan Inc	User may

05						inadvertently change the Units of Measure from mg/dL to mmol/L and the blood glucose results could be misinterpreted. This may lead to under treatment and potential for hyperglycemia.
Z-0822-05	LifeScan	1	4/11/2005	5/17/2005	Lifescan Inc	User may inadvertently change the Units of Measure from mg/dL to mmol/L and the blood glucose results could be misinterpreted. This may lead to under treatment and potential for hyperglycemia.
Z-0823-05	LifeScan	1	4/11/2005	5/17/2005	Lifescan Inc	User may inadvertently change the Units of Measure from mg/dL to mmol/L and the blood glucose results could be misinterpreted. This may lead to under treatment and potential for hyperglycemia.
Z-0276-	Hypoguard	2	11/26/200	12/25/200	Hypoguard	When actual

04	Advance		3	3	USA Inc.	blood glucose levels are in the low end of the blood glucose range the recalled test strips may provide inaccurately high readings.
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Other recalls of interest include:

Other Recalls of Interest						
Recall Number	Trade Name/Product	Recall Class	Date Posted	Date Initiated	Recalling Manufacturer	Reason for Recall
Z-1356-06	ACCU-CHEK Advantage	2	6/22/2006	8/5/2006	Roche Diagnostics Corp.	The meter gives an error message that can actually mean either a problem with the strip or a blood glucose too low to measure but the meter error message only reports that there is a strip error.
Z-1357-06	ACCU-CHEK Advantage	2	6/22/2006	8/5/2006	Roche Diagnostics Corp.	The meter gives an error message that can actually mean either a

						problem with the strip or a blood glucose too low to measure but the meter error message only reports that the test strip may be damaged or test was not performed correctly.
Z-1366-06	AccuData GTS	2	6/22/2006	8/5/2006	Roche Diagnostics Corp.	The meter gives an error message that can actually mean either a problem with the strip or a blood glucose too low to measure but the meter error message only reports that there is a bad strip.
Z-1370-06	ACCU-Chek Voicemate	2	6/22/2006	8/5/2006	Roche Diagnostics Corp.	The meter gives an error message that can actually mean either a problem with the strip or a blood glucose too low to

						measure but the meter error message only reports that there is a bad strip.
Z-1371-06	ACCU-CHEK Voicemate	2	6/22/2006	8/5/2006	Roche Diagnostics Corp.	The meter gives an error message that can actually mean either a problem with the strip or a blood glucose too low to measure but the meter error message only reports that there is a bad strip.
Z-1354-06	ACCU-CHEK Advantage	2	6/22/2006	8/5/2006	Roche Diagnostics Corp.	The meter gives a strip error message that can actually mean either a problem with the strip or a blood glucose too low to measure but the meter error message only reports that there is a strip error and the manual only

						instructs the user to retest with a new strip using a larger drop of blood.
Z-0272-06	OneTouch Ultra	3	10/10/2005	12/8/2005	Lifescan Inc	Users may inadvertently change units of measurement on demonstration kits of the OneTouch Ultra Blood Glucose Meters

The following table lists the MedSun reports that are described in the device problem summary above.

[Note: The reports have been edited for clarity]

Adverse Events		
Device	Device Identifiers	Event Description
Roche Diagnostics: Accucheck	None provided	Accucheck test that was performed read "HI." The doctor was notified and orders of 10 units of regular insulin were given. At this point, results from serum glucose test done by lab (prior to insulin administration) shows glucose levels of 253. Doctor was notified of variance and a second accucheck test was performed (35 minutes post insulin administration). Result showed 161. Accucheck equipment was then replaced at that time. Throughout, patient remained alert, oriented, pink, warm and dry
Lifescan, Inc: Sure Step Pro	Catalog: 010-797 / Lot:	Defective strips were noted to have a black band on the same side of the test strip as the pink application

	2860185 008	<p>square. Reporter notes that "a black band should not be present on that side of the test strip." Test pads on the detective test strips seemed to have been missing or very loosely attached. Confirmation dot on the back of the test strip may also have been off center.</p> <p>The manufacturer Lifescan was notified and acknowledged the problem.</p>
Roche Diag: Accucheck Inform	None provided	<p>Patient arrived to the ED via wheelchair with a family member. He was triaged with an initial complaint of a sore throat, nausea, and vomiting for a couple of days. After triage, the patient was sent to the waiting room. The nurse went to the waiting room to bring the patient back. They found the patient lying on the floor of the waiting room, lethargic but arousable. Patient noted that he wasn't feeling well. An initial blood glucose check was done (using the Accucheck device) and controls were completed. According to the device, the blood glucose check read "too low to register" and the test was repeated. Again the check read "too low to register." The physicians were informed of the results. Two ampoules of dextrose 5% were ordered and given. IV fluids of dextrose 5% were also ordered and given. Approximately 35 minutes later, the lab reported and documented that the patient's serum glucose result (prior to dextrose) was 1284. The doctor was informed and new orders for an insulin drip were given instead. IV fluid was changed to normal saline. Another blood glucose check (cannot confirm by which device) was done which registered that "results were too high." In the blood glucose history, the control reading and the high reading were present. However, the two low readings were not shown. Patient was ultimately admitted to the ICU, diagnosed as a new diabetic, and discharged six days later.</p>
Roche Diag: Accucheck Inform	None provided	<p>Nursing dropped the glucometer resulting in a break. Glucometer was taped together with scotch tape and ran for patient results. Nurse obtained a critical value and treated patient with insulin. There was no documentation of controls being performed after the meter was broken. At change of shift, the new nurse noted patient was cold and unresponsive. Patient had a blood sugar of 15. Other patients were tested with the broken device, but values obtained were within</p>

		normal ranges. These patients were ultimately retested by oncoming shift with a different meter.
Roche Diag: Accudata GTS	Lot: 3B3A09	A glucometer seemed to have reported the wrong value. On first reading value reported was high, second was 474. Patient was given 12 units of regular insulin. An hour later, the patient became very ill and the dexi was checked with the [same] glucometer. Result given was 395. Blood was drawn and sent at the same time to the lab. Lab reported a value of 5. the patient was treated to increase blood sugar. The patient's blood sugar was checked by a second machine and the result was 333. Again blood was simultaneously sent [to the lab], which reported a value of 217. Patient's condition worsened and was transferred to the IMC [intermediate care unit]. Both glucose machines showed a discrepancy between the lab value of the patient's blood glucose. After patient received a bath a dexi strip was checked and revealed a blood sugar of 474. Patient was treated with 12 units of regular insulin.
LifeScan, Inc: One Touch Glucose Control Solution	Lot: 3B3A09	The test control solution repeatedly failed quality control test on the sure step glucose monitor. Staff was able to complete quality control test with a high test control substance from a different lot number. Event was reported to internal supply chain manager for follow up.
Medtronic Minimed: Glucose Sensor	Catalog: MMT-7002 / Lot: F133	A patient was admitted with hyperkalemia and hyperglycemia related to their diabetes. The physician ordered 24 hour glucose monitoring. When the diabetic educator was inserting the glucose sensor into the abdomen and then tried to pull the needle out, the handle came off, and the needle stayed over the sensor inside the skin of the abdomen. The needle separated from the injector. Thus, the needle holder broke in two pieces after being inserted into the patient's abdomen. The sensor and broken needle were removed. A new needle was inserted without incident. The patient had to be stuck twice.
Abbott Laboratories: Precision PCX	None provided	Blood was drawn from a patient in the morning and sent to the laboratory for a glucose reading. The same glucose meter was used to test the patients glucose levels at approximately an hour later. The time on the meter read approximately three hours ahead of time. When the physician received the

		<p>results, the results indicated that the glucose levels had gone down (due to the incorrect time reading on the meter) when in reality the results had gone up. In this incident the patient was not harmed, but the potential existed for the misadministration of medication based on an incorrect meter time. Further follow up revealed that the meter clock stops when the meter is turned off. When the meter is turned on, the clock starts again thereby giving the test record a time stamp that is wrong. When the test record is uploaded to the hospital electronic medical record, the computer does not know that the time stamp is incorrect. It will sort all test records by date/time.</p> <p>When the physician reviews/compares bedside glucose test records with other meter records and lab records, it gives a false picture of the patient's response to treatment. The meter will regain the correct date/time from the hospital network when it is uploaded. however, experience has shown that the meter will lose the correct date/time again. Other causes are from the meter being dropped, bumped, etc. The meter date/time cannot be manually reset by the user. Biomed is not allowed to work with the meters. When there are problems, the vendor replaces them.</p>
LifeScan, Inc: One Touch Sure Step Pro	Lot: 261567A008	<p>Nurse discovered that the blood oval on a surestep pro blood glucose test strip was "off center" on the strip. Additionally, the tip of the strip is offset. this prevents accurate measurement when inserted into the surestep blood glucose monitor. No harm to patient was noted. All products were returned and the defective lots were replaced by the company representative.</p>
Roche Diag: Inform	None provided	<p>A patient with a history of diabetes, cardiac ejection fraction of 5%, severe peripheral edema. The blood sugar was drawn and sent to lab. The accucheck was done and the result was 486 it was repeated and the result was 338. Sliding scale insulin was given (9units). The lab results were called to floor and the results were 30. The patient went into respiratory arrest & was intubated. Three hours later the accucheck was 70, a venous blood sugar was 12. The same meter displayed results of 104 & 157 from finger stick, 137 from earlobe, and a lab result of 116 & 117. Lab QA person checked the equipment</p>

		to verify correct function of the device. The lab reports a similar occurrence where a patient who was on 21 different medications had finger stick results that did not correlate with the lab results, example: the finger stick was 570, and the lab draw was 169 40 minutes later. This was reported to Roche.
Roche Diag: Inform	None provided	<p>This hospital uses the roche accu-chek inform glucometer that can read bar codes to identify the patient. The use of the bar code technology began in June, 2005. It is possible to scan bar codes other than the patient's armband ID and activate the glucometer. Staff has scanned other facility armbands, discharged patient chart labels (causes billing error leading to our discovery of the problem) and the room mates in semi-private rooms were mixed up as well. This problem has been seen in several of our sister system hospitals. The issue most often is related to isolation patients when the staff does not want to take any more equipment than necessary into the room and contaminate it. The staff will scan a "remote" bar code on another document and then enter the patient's room. This is not positive identification of a patient. The possibility is strong that a patient will either receive incorrect insulin (not their test result) or will not get the insulin they need thereby compromising either patient's condition. An engineering control could be easily placed in the glucometer software to help correct the inaccurate scanning. The staff tends to scan the "remote" document as the order of the setup process does not make the patient's id the last thing to complete before doing the test. Current process is the staff must first enter the patient id by scanning the bar code then scan the test strip. If this order was reversed, the test strips could be left out of the isolation room but be scanned (bar code on the container, not the strip) and the staff could then id the patient's armband bar code at the bedside. This would be a safer practice. The company has resisted making this change.</p>
Becton Dickinson: Vacutainer Safety Lok	Lot: 5A2561	A student was attempting to place shield over needle prior to discarding and found it to be more difficult than normal. Follow up reveals that the student sustained needle stick and required testing (in addition to the patient). A contributing factor was

		that the student got distracted when performing task. Other staff agree that the shield process is difficult on some of the needles.
Roche Diag	Lot: 548521	Accucheck results not within acceptable range of disparity. Patient was a female admitted for respiratory failure, with a history of rheumatoid arthritis, peripheral vascular disease, osteoporosis, coronary artery disease, hypertension, developed a fungal uti. An accucheck was 384, with a second meter 182, minutes later reading was 328, and then within a few more minutes 266. Unable to verify with serum glucose due to poor access.
Roche Diag	None provided	This was a glucometer readings discrepancy. Finger stick readings read -hi out of normal, minutes later 138 and then within minutes 57. Less than a week later, a reading of 521 was noted, and then a few minutes later -111 was noted , and then a few minutes later 111 again.
Roche Daiag: Accucheck	None provided	Accucheck done with results of 382, rechecked a few minutes later showed 197, serum specimen drawn approximately 30 minutes later gave 77.
Roche Diag: Accucheck	None provided	Patient's glucose reads 394 mg/dl and insulin was given (18 units reg iv). Attempted to get a second reading and glucometer showed an error code. A second glucometer showed patient's glucose at 101 mg/dl. Dextrose 50% was given to counteract the insulin. The first glucometer was immediately shipped to the manufacturer without biomed investigating. A new unit was sent in by the manufacturer.
Abbot Lab: Medisense Precision PCX	None Provided	Facility has utilized medisense precision pcx strips for point of care glucose testing for many years. NiICU was plagued with requests from the term nurseries, and labor and delivery to retest infant's blood sugars using our i-stat device. The i-stat results were almost always significantly higher than the pcx readings. A few months ago we began using medisense precision pcx plus strips (aka: gold strips). The result was approximately a 75% drop in the number of i-stat tests being done in the NICU.
LifeScan Inc: Surestep Flex	L6132SB00012	The nurse took the fasting blood sugar at 1700 and the result was 247. Patient was treated with 5 units of regular insulin. About 15 minutes after the administration: patient's husband stated that she was

		having hypoglycemic reaction. Nurse re-checked the blood sugar and found it was 259. The physician and nurse practitioner came right away and determined that patient may be experiencing a stroke. The stroke team was called. The blood sugar was re-checked again and found to be 12. Two glucometers were used that registered the high blood sugars. Both were pulled from service and sent to the laboratory for repair. Replacements were sent to the patient care unit. Investigations as follows: 1. nurse technique appropriate. 2. question of whether the new cleaning procedure for glucose machines may be altering results. Trial is in progress. 3. patient may have had a simple insulin reaction. patient is doing well and has been discharged.
Roche Diag	Lot: UJ85002102	Discrepancies in 2 glucose readings done within minutes of each other. Compared with venipuncture glucose reading. Venipuncture value was used for treatment.
Roche Diag: Accucheck	Lot: UJ35012137	Blood glucose on accu-chek results: 166 results from lab: 259. Both tests were run on same blood sample. Accu-chek controls completed and no problems were identified.
LifeScan Inc: Suretep Flex	None provided	Glucometer read 32. After sample was rechecked with another glucometer, the sample was 168. Patient was asymptomatic. The glucometer was sent to the laboratory that oversees the maintenance.
Roche Diag: Accucheck Inform System	UJ82002422	Patient arrived to emergency room unresponsive. Accucheck glucose monitor showed a value of 93. Saline lock started and blood drawn for lab. Lab blood sugar 32. Emergency room staff concerned about difference in blood sugar results. Lab's point-of-care coordinator sent accucheck inform monitor to Roche to be checked out. lab's point-of-care coordinator feels difference can be explained by the emergency room finger stick being a capillary draw, while lab result from blood drawn from a saline lock.
Roche Diag: Accucheck Inform Monitor	Catalog: 2001201 / Lot: UJ48020502	Reporter states connector pins on meter were missing while using the inform system. Reporter states the 3rd and 4th prong were missing from the right hand side. CI investigation confirmed melting/burning of pins 3 and 4. No adverse event was reported. A request was made for return of the

		suspect product and a replacement was sent.
Abbott Labs: Medisense Precision XTRA	None provided	EMS experienced an error with a precision extra glucometer device. The ambulance crew had responded to a call at another facility for a patient with an altered level of consciousness. On their arrival the facility staff reported an initial blood glucose reading in the 40s. This facility staff had administered oral glucose and im glucagon prior to the ambulance arriving, with a recheck blood glucose reading in the 50s. The ambulance crew checked the patient's blood glucose level twice with their device and received readings of 208 and 192 respectively. The patient was transported to the hospital ED and remained unresponsive. After the call was completed it was reported to the EMS supervisor that this patient's labs showed a blood glucose level of 20 (per the hospital lab). The patient was admitted to the ICU for observation, then discharged the next day. The glucometer was immediately pulled from service, and returned to the manufacturer.
Varta Microbattery: Easy Pack Battery (for glucose meter)	Lot: 66380 712 099	This event occurred while replacing a battery in the glucose meter. While a charged battery was being placed into meter, the battery started to smoke and popped out of the meter. The battery then turned black and continued smoldering and smoking. Upon investigation, the battery was found to have burned a hole in the counter. There was no patient harm as a result, but the employee reported being bothered by the smoke from the burning battery. However, upon evaluation, no injury was identified. All batteries from this same manufacturer with the same date were removed and replaced. The manufacturer requested return of battery, meter, and docking station for analysis, and are currently pending investigation

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**Other FDA articles and notices of interest related to these POC glucose meters include:**

Overview: Glucose Testing Devices

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/GlucoseTestingDevices/default.htm>

Consumer Update: Getting Up to Date on Glucose Meters

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049051.htm>

Safety Tip: Blood Glucose Meters: Getting the Most Out of Your Meter

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109371.htm>

Safety Tip: Useful Tips to Increase Accuracy and Reduce Errors in Test Results from Glucose Meters

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109519.htm>

Safety Tip: Common Problems with the Use of Glucose Meters

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm109449.htm>

Safety Tip: Notes on Alternative Site Testing

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm070215.pdf>

Safety Alert (for laboratories and clinicians): Fatal Iatrogenic Hypoglycemia: Falsely Elevated Blood Glucose Readings with a Point-of-Care Meter Due to a Maltose-Containing Intravenous Immune Globulin Product

<http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm155099.htm>

National Diabetes Information Clearinghouse (National Institutes of Health)

<http://diabetes.niddk.nih.gov/treatments/index.htm>

### **Additional Information:**

1. Lab Tests Online: Glucose

<http://www.labtestsonline.org/understanding/analytes/glucose/glance.html><sup>45</sup>

2. Glucose Testing Devices

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/GlucoseTestingDevices/default.htm><sup>46</sup>

[Return to Top](#)

[Return to Medsun Home](#)<sup>47</sup>

**Summary of MedSun Reports Describing Adverse Events With  
Coagulation Monitoring Devices**

[Print Item](#)  
[E-mail Item](#)

*By Ahmed Haque, Patient Safety Staff, 2009*

Coagulation monitoring devices offer a way to monitor the tendency and rate of an individual's formation of blood clots. For millions of patients at risk of thrombosis or embolism, the information provided by these devices is critical in regulating the levels of anticoagulants physicians must administer. Imprecise figures or estimates can lead to dangerous results on both the high and low side of the dosing spectrum. Too much anticoagulation can lead to serious hemorrhaging and bleeding, while too little anticoagulation can lead to equally serious blood clots. Most coagulation monitors function by mixing small samples of blood via capillary or venipuncture with a set of "activating" reagents. These reagents initiate the "clotting cascade" of the blood sample. Based on how quickly the resulting blood mixture clots, the device will output a reading to be interpreted by a physician. Due to varieties in reagents and technologies used by the devices, differences in value can sometimes occur between devices. (1,2,3)

Over the past 5 years, MedSun has received 10 adverse event reports associated with coagulation monitoring devices. The reports represent the products of 5 manufacturers: International Technidyne Corporation (3), HemoSense Inc. (2), Diagnostica Stago Inc. (2), Beckman Coulter Inc. (2), and Dade Behring Inc.(1). They were submitted by 8 hospitals between September, 2004 and March, 2009.

The reported device problems include:

- Unrealistic Results / Discrepant Results (between devices): 6
- Inconsistent Results (within device): 2
- Defective Component: 1
- Monitor Blanks: 1

Of note, one report noted that the ISI value used to calculate INR results was being scanned from the bar code improperly, yielding incorrect results.

During this time period there were no reported deaths associated with these devices. Two reports indicated that treatment adjustments were based on false readings. In both reports, serious injuries resulted from the change in treatment.

The reported patient injuries include:

- Acute hemorrhaging due to high coumadin
- Syncope requiring hospitalization due to high coumadin

Of the reports that listed patient age, two had a patient age listed as less than 21 years and five had a patient age listed as greater than 21 years. Of the reports that listed patient gender, one report involved a female patient and a total of five reports involved male patients.

These MedSun reports contributed to FDA awareness of the device problems. FDA follow-up with the manufacturers may relate to the following recalls.



| <b>Recalls</b>       |                                                            |                     |                       |                    |                                |                                                                                                                                                                                                        |
|----------------------|------------------------------------------------------------|---------------------|-----------------------|--------------------|--------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Recall Number</b> | <b>Trade Name/Product</b>                                  | <b>Recall Class</b> | <b>Date Initiated</b> | <b>Date Posted</b> | <b>Recalling Manufacturer</b>  | <b>Reason For Recall</b>                                                                                                                                                                               |
| Z-1127-2007          | Instrumentation Laboratory                                 | 2                   | 6/19/2007             | 8/7/2007           | Instrumentation Laboratory Co. | ACL TOP unit when in emergency stop may release liquid during recovery sequence and contaminate sample tube.                                                                                           |
| Z-1422-05            | STA-R blood coagulation analyzer.<br>Catalog Number 57160. | 2                   | 6/20/2005             | 8/30/2005          | Diagnostica Stago Inc.         | Concerning the STA-R blood coagulation analyzer there is a possible failure mode associated with patient samples receiving prolonged exposure time to reagents during the cuvette roll change process. |
| Z-0915-05            | Instrumentation Laboratory                                 | 2                   | 5/19/2005             | 6/21/2005          | Instrumentation Laboratory Co. | Patient prothrombin time (PT) may report low for individuals                                                                                                                                           |

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|  |  |  |  |  |  | on<br>anticoagulant<br>therapy |
|--|--|--|--|--|--|--------------------------------|

The following table lists the MedSun reports that are described in the device problem summary above.

[Note: The reports have been edited for clarity]

| <b>Adverse Events</b>                                           |                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Device</b>                                                   | <b>Device Identifiers</b> | <b>Event Description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| International Technidyne Corporation: Hemochron Jr. Signature + | None provided             | Cath Lab manager reports concerns with either Hemochron Jr./Signature + machines or possibly the Cuvettes which were being utilized. At time in question, Cuvette ACT+ were being used. We are now using ACT-LR. Below is a summary of what happened, but we cannot definitively say there was a "malfunction". It was reported that while using the Cuvette ACT+, the times were lower with the amount of heparin given in some procedures. Our cath lab compared results using one blood sample between two Hemachron machines and a different mfr's machine. In one particular instance, the sample results were: The different mfr's machine read 219, Hemochron (both machines) read 171. These results were run simultaneously, side by side. The request had come from the physician when results from the same three machines, 50 minutes earlier showed the result from the different mfr's machine as 409. One of the Hemochron machines showed a result as 171 and the other Hemochron machine was not recorded. To summarize, when the cath lab used the ACT+ the times seemed to be low. We did not change our QA process and the numbers showed we were within ranges for the tests. We have since gone back to the ACT-LR and our physicians now have the confidence to believe the results. |
| HemoSense, Inc: INRatio PT                                      | None provided             | Patient with history of DVT x2, hypercoagulable state, and chronic treatment with Coumadin. Patient                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

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|----------------------------------------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Monitoring System                            |                                   | <p>was seen in Coumadin clinic where patient was tested three times. First time the machine read "error". Test was repeated two more times with result of INR 2.2 and 2.3. Patient went to a second facility for a CT scan for an unrelated issue. CT results demonstrated acute hemorrhage with the right intrarenal collecting system. Patient went to Emergency Department with complaint, and INR result via venous draw was 10.8. Patient was treated with vitamin K and fresh frozen plasma. Patient was discharged with an INR of 2, and on Coumadin 5 mg. Patient's prior Coumadin dose was 40 mg and had been increased to 90 mg based on results obtained from HemoSense monitor.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| HemoSense, Inc: INRatio PT Monitoring System | None provided                     | <p>The patient has a history of post-op DVT and pulmonary emboli diagnosed five weeks ago after ventral hernia repair. They were treated with IV unfractionated Heparin and Coumadin at that time. He was eventually stabilized on oral Coumadin and was discharged home with instructions to continue with Coumadin 5mg po every night, and to have daily PT/INR levels called to the physician. A day prior to the event, the PT/INR level was obtained per fingerstick and the level was 1.6. The physician was contacted and he increased the Coumadin dosage to 15mg. The patient had been participating in physical therapy at home. The next day, the patient was noted to have left back pain, and shoulder discomfort along with generalized weakness. He suffered a syncopal episode and was transported to the hospital. His lab results included an hemoglobin (9.1) and hematocrit (27.1). The platelets were 199,000 and the INR was 10.5. The patient was admitted to the ICU and given Vitamin K. There were two separate HemoSense machines that could have been used and both are sequestered and will be analyzed.</p> |
| Diagnostica Stago, Inc: STA Compact          | None provided                     | <p>INR results for eight days were reported out incorrectly. The ISI (International Sensitivity Index) value, which is uploaded by bar code into STA Compact was read incorrectly by the instrument. The INR (International Normalized Ratio) result is a calculated result which was reported incorrectly.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Dade Behring, Inc: CA-1500 CP                | Model: CA-1500 / Lot: Batch A4794 | <p>Patient samples were not reproducing or were causing errors on the instrument. Bubbles were noticed on the sample plate affecting the volume of</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

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|------------------------------------------------------------------------------|----------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                              |                      | <p>patient specimen being tested. Multiple manufacturer service representative visits have still not solved the problem. Dade Behring's advice was to run the specimen in duplicate, which is not required per the operator's manual. The instrument used previously did not require duplicate testing. Humidity levels and specimen collection tubes have also been mentioned as possible causes for the erroneous results. Humidity levels in the lab have been increased as high as possible with no changes.</p>                                                                                                                                                                                                                                                                                                                                                                               |
| <p>International Technidyne Corporation:<br/>Hemochron Jr.<br/>Signature</p> | <p>None provided</p> | <p>The hospital ran out of low range cuvettes for the device on 5/2005 when 2 patients were being tested at the same time. The manufacturer placed our order on back-order and instructed the staff to use the high range cuvettes, and reprogram the device to the high range control. They instructed staff that the results would be 20 - 25% lower using the high range cuvettes since the range is broader and this was to be taken into consideration. The patient was receiving blood products during this time as well as in response to their diagnosis. By the following week the manufacturer had located the low range cuvettes and they were shipped to our hospital. Follow up reveals that the device was reprogrammed for the low range cuvettes. Now that the low range cuvettes are being used the results are not consistent when compared to results from the central lab.</p> |
| <p>International Technidyne Corp:<br/>Hemochron Jr.,<br/>Signature</p>       | <p>None provided</p> | <p>The quality controls required before use of the Hemochron Jr. and the numbers obtained were appropriate. Subsequently, the Hemochron Jr was used to obtain an Activated Clotting Time, ACT, on a patient undergoing an angioplasty. Patient was given 2000 Units of heparin and device displayed an ACT = 152. Twenty-five minutes later, the patient was given another 1000 Units of heparin and device displayed ACT = 152. After 20 minutes, another 1000 Units of heparin were given to the patient and the ACT obtained was 169. The anesthesiologist who was monitoring the patient reports that after 4000 Units of heparin, the patient's ACT should have been approximately 200. A PTT, prothrombin time, requested from lab at the same time was greater than 106 seconds.</p>                                                                                                        |
| <p>Beckman Coulter, Inc:</p>                                                 | <p>Model: E1400C</p> | <p>This event involved the heat exchanger and tubing for MLA 1400C coagulation instrument. After a</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

|                                                                   |                |                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------------------------------------------|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MLA 1400 C                                                        |                | long period of problems with quality control and checking everything the problem was finally narrowed down to the heat exchanger and tubing. The company acknowledged that they had changed manufacturers.                                                                                                                                                                                                                                                |
| Beckman Coulter, Inc:<br>Electra 1400C<br>coagulation<br>analyzer | Model: E1400 C | Screen monitor went blank. Beckman Coulter service person replaced monitor. Machine down 24 hours.                                                                                                                                                                                                                                                                                                                                                        |
| Diagnostica Stago, Inc:<br>Compact                                | None provided  | Sample was put on coagulation instrument to test a PTT, partial thromboplastin time. First result was greater than 300 seconds. Instrument automatically repeated the test and resulted as greater than 300 seconds for the second time. Sample was checked for clot and result turned out. No clot was found. Sample was centrifuged and repeated. Again, first result was greater than 300 then instrument auto-repeated with a result of 79.8 seconds. |

#### **Additional Information:**

##### **1. Lab Tests Online**

<http://www.labtestsonline.org/understanding/analytes/pt/test.html><sup>48</sup>

2. Hirsh, J. & Fuster, V. Guide to anticoagulant therapy. Part 2: Oral anticoagulants. American Heart Association [published erratum appears in Circulation 1995 Jan 15; 91 (2): A55-A56]. Circulation 89, 1469–1480 (1994).

<sup>49</sup>

3. Yang, D.T., Robetorye, R.S. & Rodgers, G.M. Home prothrombin time monitoring: a literature analysis. Am. J. Hematol 77, 177-186 (2004).